Harvey Winkler

Supplemental General Reliance List
in Addition to Materials Referenced in Report

MDL Wave 4

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Medical Literature

Description
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Document Description [Bates Range]
(09.06.2006) - Peter Meier LIGHTning Presentation.
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
Athos/Aramis/Porthos, Concept - Feasibility , June 27, 2003
Brief Summary pf the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee - Meeting February 25, 2016.
Clinical Evaluation Report - Gynecare Prolift signed by P. Hinoul on 04.26.2013
Correspondence between Morgan Liscinsky of FDA & Bloomberg re: Johnson & Johnson Vaginal Mesh Implant.
Document re: porosity of Gynemesh PS
ETH.MESH.00001595-606 - Reisenauer, C., et al. Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. Eur J Obstet Gynecol (2006).
ETH.MESH.00004781-786 - Prolift +M: Biocompatibility is the science of living better.
ETH.MESH.00012009-089 - Clinical Study Report: Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse.
ETH.MESH.00016032-039 - Kohli, N., et al. Augmenting pelvic floor repairs: new materials and techniques. OBG Management (2006) S1-S8.
ETH.MESH.00017073-078 - Sola, et al. Tension Free Monofilament Macropore Polypropylene Mesh (Gynemesh PS) in Female Genital Prolapse Repair. Clinical Urology (2006) 32(4): 410-415
ETH.MESH.00017362-368 - Elmer C, et al. Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery, J Urol (2009), 181 (3), 1189-95.
ETH.MESH.00017553-560 - Tunuguntla, H. Female Sexual Dysfunction Following Vaginal Surgery: A Review. Journal of Urology 2006; 175: 439-446
ETH.MESH.00018344-479 - Gynemesh PS Prof Ed Slide Deck 2007
ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00031538 - Presentation: Gynecare Professional Relations and Professional Education “Educating Customers Worldwide to improve the lives of women”
ETH.MESH.00086463-464 - Email from P. Hinoul to Z. Viana, et al. re: Prosima take away messages.
ETH.MESH.00088927-939 - 2007 ACOG Practice Bulletin No. 85 re: Pelvic Organ Prolapse.
ETH.MESH.00126755-757 - Email string, top one from M. Yale to J. Paine, et al. re: Draft FDA response on Prolift+M for input
ETH.MESH.00133502-504 - (11.23.2005) Email string, top one from Quentin Manley to multiple recipients re: Prolift improvements - Professor Eberhard (Fraunenfeld, Switzerland).
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP - Pelvic Floor Surgery and Anatomic Dissection Lab
ETH.MESH.00167104-110 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00267733-872 - (12.12.2006) Lightning Project Charter
ETH.MESH.00271215-216 - Email from J. Meek to multiple recipients e: Pre-Reading for Prolift+M: Internal Use Only. Not Copy Reviewed or For Distribution
ETH.MESH.00273967 - Email from Clifford Volpe to Scott Jones re: slides for Pelvic Floor Summit.; Powerpoint: R&D Perspective - The Journey from Prolift to Prolift +M.

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ETH.MESH.00349226-237 - May 26, 2000 Ethicon Memo to P. Cecchini RE: Review of Biocompatibility Data on the Tension Free Vaginal Tape (TVT) System for Compliance to FDA G-95/ ISO 10993/ EN 30993
ETH.MESH.00365412-414 - June 14, 2007 Memo RE: ADDENDUM: Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
ETH.MESH.00372341-357 - Letter from B. Lisa to J. Dang reL K071512 S02 (09.20.2007)
ETH.MESH.00372664-671 - Letter from B. Lisa to J. Dang re: K071512 S04. (02.21.2008)
ETH.MESH.00395374-380 - Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes Chicago, IL June 22, 2001
ETH.MESH.00442831-834 - (01.18.2005) Email string, top one from Kelly Brown to Gene Kammerer, et al. re: Proposal for work with CBAT.
ETH.MESH.00461576 - 10.23.2006 letter to EWHU field sales force
ETH.MESH.00467706-709 - (08.27.2007) Email string, top one from Price St. Hilaire to V. Lucente, et al. re: OBG Management/Pelvic Health Coalition supplement - Final.
ETH.MESH.00584846-847 - (05.10.2004) Email string, top one from Gene Kammerer to Mora Melican, et al. re: Mesh for TVM.
ETH.MESH.00584847 - (05.10.2004) Email string, top one from Gene Kammerer to Mora Melican, et al. re: Mesh for TVM.
ETH.MESH.00585229 - (01.14.2005) Email from Gene Kammerer to Dr. Dieter Engel re: UltraPro for Pelvic floor repair.
ETH.MESH.00585688-690 - Use of UltraPro Mesh for Pelvic Organ Prolapse (POP) Repair through a Vaginal Approach.
ETH.MESH.00585937-939 - (02.13.2006) Email string, top one from Gene Kammerer to Quentin Manley, et al. re: TVM discussions.
ETH.MESH.00596225 - Sikirica, V., et al. A systematic review of the Gynecare prolift pelvic floor repair system in pelvic organ prolapse. Int Urogynecol J (2010).
ETH.MESH.00656714-716 - Email from O. Berthier to multiple recipients re: Update on Prolift CD rom
ETH.MESH.00719198-209 - (02.06.2007) Email string, top one from Kevin Mahar to Linwood Staub re: ACOG Practice Bulletin on Pelvic Organ Prolapse.
ETH.MESH.00835753-755 - (11.30.2006) Email string, top one from David Robinson to Clifford Volpe re: changes Cosson and Jacquetin want made to Prolift.
ETH.MESH.00851319-321 - Email string, top one from P. Hinoul to C. Volpe, et al. re: Prosima implant dimensions.
ETH.MESH.00855158-159 - (12.17.2007) Email from Peter Meier to Clifford Volpe, et al. re: Explant database for Pelvic Floor Meshes.
ETH.MESH.00870466-476 - (06.02.2006) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.
ETH.MESH.00911305 - Memo re: PDD Requirement 2.3.2 pertaining to clinical evidence (11.22.2004).
ETH.MESH.00922443-446 - Email string, top one from P. St. Hilaire to B. Lisa, et al. re: Bidirectional elasticity statement
ETH.MESH.00989774-775 - History of TVM, Development of the Technique.
ETH.MESH.01154031-37 - Clinical Expert Report - Gynemesh Prolene Soft
ETH.MESH.01218423-424 - Pelvic Organ Prolapse Repair: Lesson Learned from the Prolift Experience.
ETH.MESH.01264260 - Prolift +M Piet Hinoul Pelvic Floor Meeting Nderland Utrecht, May 7, 2009
ETH.MESH.01274741-743 - Use of UltraPro Mesh for Pelvic Organ Prolapse (POP) Repair through a Vaginal Approach.

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ETH.MESH.01314498-505 - Memo re: Prolift Design Review: Design Verification, Process Qualification and Design Transfer - Review Minutes and Action Items (02.28.2005).
ETH.MESH.01428106-112 - Carvigni, M. The use of synthetics in the treatment of pelvic organ prolapse. Curr Opin Urol 2001; 11: 429-435.
ETH.MESH.01716847-848 - (03.20.2007) Email string, top one from Bart Pattyson to Dr. Hilary Cholhan re: response to ACOG bulletin.
ETH.MESH.01733531-535 - Kasturi, S. Pelvic magnetic resonance imaging for assessment of the efficacy of the Prolift system for pelvic organ prolapse. Am J Obstet Gynecol 2010; 203: 1.e1-1.e5
ETH.MESH.01760853-861 - Clinical Expert report (not signed): UltraPro Mesh for Pelvic Organ Prolapse through a Vaginal Approach.
ETH.MESH.01782114-115 - (05.03.2006) Email string, top one from David Robinson to Carolyn Brennan re: Suzette email discussing problems with Prolift.
ETH.MESH.01782783-785 - (02.02.2006) Notes from meeting with Dr. V. Lucente and Dr. M. Murphy (Allentown, PA) to discuss Prolift RCT.
ETH.MESH.01782854-866 - 2007 ACOG Practice Bulletin No. 79 re: Pelvic Organ Prolapse.
ETH.MESH.01785259-260 - (01.17.2010) Email string, top one from Piet Hinoul to David Robinson, et al. re: Prolift+M relaxation.
ETH.MESH.02001398-404 - Gynecare Prolift IFU (English Only)
ETH.MESH.02017152-158 - (02.23.2007) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.
ETH.MESH.02059150-151 - May 24, 2006 Memo RE: First Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
ETH.MESH.02089443-446 - Meeting of the Group TVM, Paris, September 29, 2013.
ETH.MESH.02211912 - Annex 11: Porosity test on finished product - pelvic floor mesh.
ETH.MESH.02215374-375 - Jacquetin B. Prolene Soft (Gynecare) Mesh for Pelvic Organ Prolapse Surgical Treatment: A Prospective Study of 264 Patients. Abstract 767
ETH.MESH.02215565-567 - Email from Scott Ciarrocca to multiple recipients re: a message from Barbara Schwartz re: Prolift (01.02.2005).
ETH.MESH.02219584 - Scion PA-SUI Treatment Unmet Needs Exploratory Research
ETH.MESH.02232854-874 - Prolift+M - Advanced User Discussion
ETH.MESH.02233126-187 - Prolift+M Educational Module
ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh_Particle loss less than 2 percent for both
ETH.MESH.02270363-365 - (04.14.2005) Email string, top one from Ophelie Berthier to Scott Ciarrocca, et al. re: TVM group meeting.
ETH.MESH.02270724 - (07.19.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: Gynemesh holding force in tissue.
ETH.MESH.02270766-767 - (11.21.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: D'Art, risk question.
ETH.MESH.02270857-858 - (07.16.2004) Email from Laura Angelini to multiple recipients re: D'Art - Conversation with Prof. Jacquetin.
ETH.MESH.02280771-772 - Email string, top one from S. O'Bryan to S. Ciarrocca, et al. re: D'Art clinical expert report (CE Mark requirement)
ETH.MESH.02282833-834 - Email from S. Bell to multiple recipients re: TVM - First training - key learnings
ETH.MESH.02286052-053 - Email string, top one from S. O'Bryan to S. Ciarrocca re: Prolift IFU
ETH.MESH.0232094-96 - Prolene Soft IFU (8.23.2010-Present)
ETH.MESH.02341454-459 - Gynecare Prolift IFU (English Only)

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ETH.MESH.02341522-527 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341658-664 - Gynecare Prolift IFU (English Only)
ETH.MESH.02342102 - Prolene mesh IFU (05_29_1999 until 5_19_2015)
ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02391355-56 - Miller, D., et al. Prospective clinical assessment of the total vaginal mesh (TVM) technique for treatment of pelvic organ prolapse - 6 and 12 month results.
ETH.MESH.02589032-079 - (05.18.2011) Investigating Mesh Erosion in Pelvic Floor Repair.
ETH.MESH.02596085 - Letters to the Editor 2010; 1457
ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh
ETH.MESH.02766191-192 - (01.12.2006) Minutes of telephone conference.
ETH.MESH.02923305-306 - (08.15.2005) Email string, top one from Anne Doherty to Kimberly Hunsicker re: Prolift.
ETH.MESH.03259876-877 - (09.21.2005) Email string, top one from Judith Gauld to Jessica Shen re: TVM 6 month data.
ETH.MESH.03354810-811 - Project D'Art, Clinical Strategy, March 20, 2004.
ETH.MESH.03361293 - Mesh Platform Review: Somerville, November, 2010.
ETH.MESH.03460813-853 - Prolift Surgeon's Resource Monograph, approved 4.13.2007
ETH.MESH.03495151 - (09.01.2005) Letter (redacted) re: Product: Gynecare Gynemesh, Event Date: 05/2005, Reference #10034737.
ETH.MESH.03576207-208 - (08.09.2005) Email from Martin Weisberg to Carol Holloway re: File #10034737.
ETH.MESH.03667696-704 - Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices.
ETH.MESH.03736120-127 - Gynemesh PS: A New Mesh for Pelvic Floor Repair Early Clinical Experience
ETH.MESH.03903827-829 - Project TVM (Trans Vaginal Mesh)
ETH.MESH.03905968-975 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03905976-991 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03906037-052 - Prolift Patient Brochure: Treatment Options for POP, stop coping, start living
ETH.MESH.03910637-638 - Email string, top one from A. Arnaud to W. Van Dijk re: critical Q&A.
ETH.MESH.03911901-910 - Deprest J, et al. The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. Int Urogynecol J (2006)
ETH.MESH.03915588-590 - (04.12.2005) Email string, top one from Gene Kammerer to Ronnie Toddywala, et al. re: Ultrapro.
ETH.MESH.03917375-378 - (11.26.2002) Email string, top one from Martin Weisberg to Dr. Richard Juraschek, et al. re: Mini TVT - mesh adjustment.
ETH.MESH.03921355-156 - Miller, D. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results.
ETH.MESH.03923931-934 - Press Interview, Frankfort, June 9, 2005.
ETH.MESH.04551757-795 - Email from P. Hinoul to J. Hammond, et al. re: benefit risk profile for TVM

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ETH.MESH.04552528-529 - Email from P. Hermansson to multiple recipients re: FDA Health Notification relating pelvic floor repair mesh kits
ETH.MESH.04558399-409 - Iglesia C. Vaginal Mesh for Prolapse: A Randomized Controlled Trial. Obstet Gynecol 2010;116:293-303
ETH.MESH.04945231-239 - (04.14.2005) Email string, top one from Dr. Joerg Holste to Thomas Barbolt, et al. re: UltraPro vs Prolene Soft Mesh.
ETH.MESH.05217145-149 - Flow chart re: Gynecare Prolift
ETH.MESH.05243256-259 - (11.09.2005) Email string, top one from Gene Kammerer to Dr. Dieter Engel, et al. re: Gynemesh PS w/Monocryl.
ETH.MESH.05479535 - Type of meshes by category: microporous, medium, macroporous.
ETH.MESH.06382976-987 - Jia, X. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis. BJOG 2008; 115: 1350-1361
ETH.MESH.06593827-829 - Letter to Gorsky re: Prolift decommercialization decision
ETH.MESH.06828907-909 - (03.24.2005) Email string, top one from Kimberly Hunsicker to Laura Angelini, et al. re: ICS submission.
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